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EXAMINER

GARG, YOGESH C

ART UNIT PAPER NUMBER

3625

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/632,124

Applicant(s)

PUBLICOVER, MARK W.

Examiner

Yogesh C Garg

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

35 U.S.C. 101 and 35 U.S.C. 112, First Paragraph

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16 and 18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter because:

1.1. System claim 18 recites within their scope a human being.

Claim 18 recites the limitation that the system comprises, " (b) a plurality of member individuals", wherein orders are received from these plurality of member individuals. A claim directed to or including within its scope of a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. The applicant's attention is kindly referred to recent ruling by the US Patent and Trade Mark Office, Board of Appeals and Interferences (Ex Parte Bowman, 61 USPQ2d 1669) (Unpublished)) .

An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties or combination not present in the original article existing in nature In accordance with existing law. -See e.g. Funk Bros, Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 76 USPQ 280 (1948); American Fruit Growers v. Brogdex. 283 U.S. 1, 8 USPQ 131 (1931); Ex parte Grayson. 51 USPQ 413 (Bd. App. 1941).

A claim directed to or including within its scope a human being will not be considered to be Patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, It is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope include the limitation "non-human" to avoid this ground of rejection. The use of a negative limitation to define the metes and bounds of the claimed subject matter is a permissible form of expression. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

1.2 Claim 16 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claim 16 is a one line statement and specifying no utility.

1.3. Claim 16 recites a single means, that is " an item exchange site" and, therefore, is also rejected under 112, first paragraph, see MPEP: 2164.08(a) Single Means Claim:

A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. *In re Hyatt*, 708 F.2d 712, 714-715, 218 USPQ 195, 197 (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to *Hyatt* is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 12, 14-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Lester et al. (US Patent 6,021,392), hereinafter, referred as Lester.

Regarding claim 1, Lester discloses a method of distributing at least one item to a first individual, the method comprising:

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(a) receiving an order from the first individual for the at least one item (see at least col.3, lines 49-58, "*receive an electronic purchase order from the first computer*". Note: First computer corresponds to the first computer of an individual. Also, see col.8, lines 16-51.),

(b) generating an order packet corresponding to the order of the first individual (see at least col.3, lines 26-48, "*.....The present invention includes a a package containing at least one drug and the package has information.....*". Note: The invention generates this package in response to receiving an order from the first computer. Also, see col.8, lines 16-51.) ,

(c) in response to the order packet, shipping the at least one item to a consolidating distribution center, (d) packaging the at least one item and labeling the at least one item so as to be identifiable as intended for the first individual, thereby producing a shipment, and (e) transporting the shipment to a substantially unattended secure designated item exchange site (DS) from which the first individual or a first designated agent can retrieve the shipment (see at least lines 25-51, "*In accordance with a preferred embodiment of the present invention, the CPC 20 generates an electronic purchase order that is sent to the DCC 12. The purchase order contains a request for a bulk purchase of one or more varieties of drugs The DCC 12 acknowledges the purchase order and fills the requested order. The DCC 12 produces an invoice for the bulk order and sends the invoice to the CPC 20. In a preferred embodiment, the distribution center ships the requested unit dose packages of drugs in "totes" (shipping containers, bags, boxes or other suitable containers) 60 which are predesignated for a particular DDM 18 at the health care facility. Therefore, instead of the health care facility having to spend resources on getting the right drugs to the right DDM 18, the DCC 12 can accomplish this in a much faster manner through its tracking of data received from the CPC 20 (which received its data, in part,*

from each DDM 18) and the subsequent shipping of predesignated and properly labeled totes 60. The outside of each tote 60 may also contain bar code information for easy tracking of totes 60 as they are sent from the distribution center and received at the health care facility. " Note: DCC 12

corresponds to the consolidating Distribution center, DMM 18 corresponds to the substantially unattended secure designated item exchange site (DS) from where the ordering agency/individuals can retrieve the shipments. Also see col.4, line 63-col.6, line 58 which describes that the DMM 18 is an unattended drug packages dispensing machine (DS) and is also automated to communicate with the central computer 20 and further includes data entry means such as key-pad .), and

(f) repeating steps (a) through (e) inclusive for a second individual in place of the first individual, using the same DS (see at least col.5, lines 46-53 which teaches that each DDM can cater to several patients in a health care facility which implies that order being received for a second patient corresponds to order for second individual and for which all steps a through e will be repeated.

Regarding claims 2-3, Lester discloses that the DS is at least semi-automated/ fully automated(see col.4, line 63-col.6, line 58 which describes that the DMM 18 is an unattended drug packages dispensing machine (DS) and is also automated to communicate with the central computer 20 and further includes data entry means such as key-pad .).

Regarding claim 12, Lester teaches that the labeling is accomplished by a labeling device that comprises information relating to the individual, the individual

personal identifier, the order, the at least one item, the secure designated site, the consolidated distribution center, the shipment or the order packet (see at least Lester Figs. 3A, 11, 12, 13 and 14, col.14, lines 14-50, " a bar coded label is attached that identifies the contents of the package 30; and (b) checking that the bar coded label on the bag or package 30 accurately represents the contents of the package 30 and that the contents are suitable for use in the station 18 ("suitable" means that the packaging is intact, item is not out of date, or otherwise unfit for its intended use); (2) receiving pre-prepared items from a distribution center in station specific totes; and (3) delivering bagged/packaged items from the pharmacy or directly from a distributor to the correct pocket in a DDM 18..... The following labels are used in the system 10 and are produceable on the portable printer: (1) shelf labels to identify shelf stock for the picking process; Examples of these labels are shown in FIGS. 11-13. " and col.16, lines 30-37, " *Bag/Package Label: The bag/package printed during the picking activity in the pharmacy preferably contains in bar code form the local item identifier, the picked quantity, and the picked serial number. The bar code uses a data identifier to differentiate this bar code from any other kind. An example of a bag/package label is shown in FIG. 11. "*

Regarding claim 14, Lester teaches that there is a multiplicity of items Distributed (see at least col.13, lines 10-12, "*When the supplier 12 receives a purchase order from a hospital, the ordered drugs are loaded... . "* Note: The plurality of drugs correspond to multiplicity of items being distributed.)

Regarding claim 15, Lester discloses a first item originates from a first supplier and a second item originates from a second supplier (see at least col.2, lines 3-5, ".....*traditionally purchased drugs from drug distributors...*". Note: purchasing drugs from a

plurality of drug distributors suggest that a second item can originate from a second supplier).

Regarding claim 16, the limitations of a substantially unattended secure designated item exchange site (DS is already covered in claim 1.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3.1. Claims 4-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lester in view of Porter (US Patent 6,426,699) and further in view of Official Notice.

Regarding claims 4-9, Lester does not teach that the method of claim 1, further comprising accessing the DS by the individual through use of a personal identifier in order to retrieve the shipment, wherein the personal identifier identifies the individual at least in part through information chosen from the group consisting of biometric, numeric, alpha-numeric, alphabetic, physical, statistically assigned and randomly assigned, wherein the biometric information is chosen from the group consisting of a

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retinal scan, a digital thumb print, a voice print, a chemical skin print, a pheromone print, a genetic print, an odor print and combinations thereof, wherein the personal identifier is encoded in a physical key, wherein the physical key is chosen from the group consisting of a key card and a biological sample, wherein the biological sample is chosen from the group consisting of sweat, blood, spittle, breath, hair, dermal cells, dermal cell contact and mixtures thereof. However, Porter in the same field of endeavor teaches the missing limitations (see at least col.3, lines 55-67, "*As illustrated in FIG. 11, the storage device 10 includes a lock 56 for locking the door 42 and a lock operator 58 for locking and unlocking the lock. In preferred forms, the lock operator includes an input device such as a alphanumeric keypad 60 for permitting the entry of keycodes. As described in more detail below, the lock operator unlocks the lock only when a correct keycode is entered into the keypad. The lock operator also may be coupled with other types of entry controlling devices such as a card reader, voice recognition device, fingerprint identification system, infrared sensor, bar code reader, or radio signal controlled or contactless smart card having a computer microchip embedded thereon, or the like.*"

Note: the storage device 10 for packages corresponds to DS in the claimed application or DMM 18 in Lester from where the packages are retrieved by using a personal identifier either biometric or numeric or alphanumeric, or physical key. Lester in view of Porter does not disclose some of the identifiers, viz: retinal scan, a chemical skin print, a pheromone print, a genetic print, an odor print and combinations thereof, and a biological sample, wherein the biological sample is chosen from the group consisting of sweat, blood, spittle, breath, hair, dermal cells, dermal cell contact and mixtures. However, the examiner takes an Official Notice for the missing identifiers as those were well-known identifiers being used for authentication.

In view of Porter and the Official Notice taken by the examiner, it would have been obvious to one of an ordinary skill in the art at the time of the applicant's invention to have incorporated the features of accessing the DS by the individual through use of a personal identifier in order to retrieve the shipment, wherein the personal identifier identifies the individual at least in part through information chosen from the group consisting of biometric, numeric, alpha-numeric, alphabetic, physical, statistically assigned and randomly assigned, wherein the biometric information is chosen from the group consisting of a retinal scan, a digital thumb print, a voice print, a chemical skin print, a pheromone print, a genetic print, an odor print and combinations thereof, wherein the personal identifier is encoded in a physical key, wherein the physical key is chosen from the group consisting of a key card and a biological sample, wherein the biological sample is chosen from the group consisting of sweat, blood, spittle, breath, hair, dermal cells, dermal cell contact and mixtures thereof **because** that would enable authorized people to retrieve the packages and would not allow access to unauthorized people.

Regarding claims 10-11, Lester does not disclose comprising triggering a notification system upon accessing the secure designated site or retrieval of the shipment wherein the notification system notifies at least one party chosen from the group consisting of an item supplier, a distribution center, a consolidated distribution center and the individual. However, in the same filed of endeavor, Porter teaches these limitations (see at least col.4, lines 1-12, " *In preferred forms, the storage device 10 also*

includes a communication and control apparatus 62 for controlling access to the device and for providing notification that goods have been delivered to or picked up from the device. As illustrated in FIG. 11, The communication and control apparatus is described in more detail in U.S. Pat. No. 5,774,053, which is incorporated herein by reference. ", and col.5, lines 13-21 "

The communication and control apparatus 62 is preferably part of a delivery system that allows messages to be sent to and received from several locations remote from the enclosure. For example, a remote communications apparatus may be placed in the homeowner's home and another remote communication apparatus may be positioned in a vendor's business. ").

In view of Porter, it would have been obvious to one of an ordinary skill in the art at the time of the applicant's invention to have incorporated the feature of triggering a notification system upon accessing the secure designated site or retrieval of the shipment wherein the notification system notifies at least one party chosen from the group consisting of an item supplier, a distribution center, a consolidated distribution center and the individual **because** such notification would inform the customer of the arrival of the package so that he can pick up and at the same time enable the vendor to charge the customer.

3.2. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lester in view of Eggleston et al. (US Patent 6,061,660), hereinafter referred to Eggleston.

Regarding claim 13, Lester does not disclose that the labeling comprises providing a smart chip. However, Eggleston discloses that the labeling comprises providing a smart chip to solve the same problem as faced by the applicant of providing information in a smart card embedded with a chip (see at least col.13, lines

29-42, " *Once a consumer has registered as a consumer member of the host system, the consumer's name, address, password, and PIN may be sent to a third party provider of electronic payment cards. The electronic payment card provider may then issue the card 11 to the consumer. The card 11 may have a magnetic strip coded for the PIN number or password that links the consumer to the consumer's entry in the consumer database 200. The card 11 may be any conventional electronic payment card, or may be a microchip-embedded smart card, in which case additional data selected from the consumer database 200 may be included for access by retailers verifying prize information.* ". Also, see col.22, lines 37-48 and col.41, line 66-col.42, line 32. In view of Eggleston, it would have been obvious to one of an ordinary skill in the art at the time of the applicant's invention to have incorporated the feature of providing labeling information in a smart chip because , as shown in Eggleston, card embedded with smart chip could be of any one of the types , such as ATM card, or credit card, etc. which enables to store identification information, about the user or any other object, such as a package and also any other additional information which can be used later to check/authenticate the individual or package and also know other relevant information stored therein.

3.3. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lester in view of Tsukuda et al. (US Patent 6,061,660), hereinafter referred to Tsukuda.

Regarding claim 17, Lester does not suggest that in the method of claim 1, wherein the first and second individuals must be members of a members-only distribution system. However, in the analogous field of endeavor Tsukuda discloses

that the first and second individuals must be members of a members-only distribution system (see at least col.7, lines 38-46, *"In a step 1001 in FIG. 10, the information inputted from the input apparatus is registered into the commissioned goods information 125. For example, in case that the information inputted from the input apparatus is "contract code: 2529, purchased goods: book, electronic address of distributor: info@a-butu.co, electronic address of purchaser: tsukuda@aaa.bbb" as shown in FIG. 9, the day when those information are inputted is treated as the day of arrival so as to set the commissioned goods information 901."*). Note: Registering the information of purchasers corresponds to the fact that they become members because all the purchasers are required to register them .). In view of Tsukuda, it would have been obvious to one of an ordinary skill in the art at the time of the applicant's invention to have incorporated the feature of making the first and second individuals as members of a members-only distribution system because , as shown in Tsukda, because it enables the system to provide services to users whose personal information, such as names, addresses, telephone numbers/e-mail, etc. are known which makes it convenient and possible to communicate with them as and when required.

Regarding claim 18, Lester in view of Tsukuda discloses a members-only distribution system. The limitations comprising (b) a plurality of member individuals; (c) at least one consolidating distribution center (CDC); (d) at least one substantially unattended secure designated item exchange site (DS); and (g) an order from a first member for at least one item to be distributed by the system are already in claims 1 and 17 and are analyzed on the basis of same rationale.

Lester further discloses (a) a computer capable of monitoring the distribution system (see at least abstract, " *A system is described in which a drug distribution center operates a computer software drug inventory management program in electronic communication with a health care provider computer software program for drug and health care supply distribution to patients.* "; (e) at least one manufacturer capable of supplying at least one item to be distributed by the system, (see at least , " *For example, the drug manufacturer's lot number 34, the variety of the drug 36, and the expiration date 38 of the drug may be printed or otherwise placed on the package 30.* ").

Lester also discloses making shipments , see col.8, lines 35-41, " *order contains a request for a bulk purchase of one or more varieties of drugs..... In a preferred embodiment, the distribution center ships the requested unit dose packages of drugs in "totes" (shipping containers, bags, boxes or other suitable containers) 60 which are predesignated for a particular DDM 18 at the health care facility.* ", and it will be obvious that the shipment will need transport vehicles to transport the "totes" containing the ordered items, that is drugs from the distribution center to the ordering entity and for many many orders and bulk shipments the need could be for a plurality of transport vehicles.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

(i) US Publication 2001/0016819 to Kolls (see at least abstract, " *The present invention allows a user to obtain authorization for use, pay for products and services, and configure the vending equipment with a smart card, or magnetic card (card). Magnetic cards include phone, smart card, credit card, debit card, pre-paid, automated teller machine (ATM) or other bank or private issued card.*

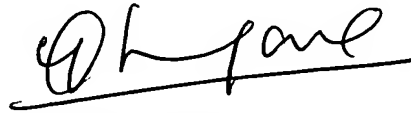
Users can also use a hotel room key/card or other insertion type-identifying device. Additionally, biometric identification such as handwriting, voice, finger, hand, or eye (iris scan) can be utilized to control the system. “) and US Patent 5,608,387 to Davies (see at least col.1, lines 21-34, “
.....*Access control systems are generally linked to personal identification devices, and many such systems and devices are known. Personal identification devices may be physical, such as key devices (e.g. encoded cards) or identity cards, or abstract, such as memorised passwords or personal identification numbers (PINs). Any system that relies on the possession of a physical device is at risk of being compromised by transfer of the device to unauthorised users, deliberately or by loss or theft, or damage to the device. These factors impose considerable burdens on system administrators to ensure that passwords and PINs are frequently changed and that operating standards are kept high enough to ensure that the integrity of the system is not broken.* “), disclose or suggest the limitations directed to personal identification by biometric or numeric or cards/physical keys, etc. as stated in claims 4-9.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yogesh C Garg whose telephone number is 703-306-0252. The examiner can normally be reached on M-F(8:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wynn Coggins can be reached on 703-308-1344. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Yogesh C Garg', written over a horizontal line.

Yogesh C Garg
Primary Examiner
Art Unit 3625

YCG
January 16, 2005